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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

HANSEN BEVERAGE COMPANY, a Delaware corporation,

Plaintiff,

v.

INNOVATION VENTURES, LLC dba LIVING ESSENTIALS, a Michigan corporation,

Defendant.

CASE NO. 08-CV-1166 IEG (POR)

HANSEN BEVERAGE COMPANY'S MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS DEFENDANT'S AMENDED COUNTERCLAIM

Date: December 14, 2009
Time: 10:30 a.m.
CrtRm: 1

Hon. Irma E. Gonzalez

Oral Argument Requested

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I
INTRODUCTION AND SUMMARY

When Innovation Ventures, LLC dba Living Essentials ("Living Essentials") filed its original counterclaim, it claimed that Hansen Beverage Company ("Hansen") was guilty of misbranding and adulteration of almost two dozen products. Living Essentials alleged violations of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FDCA"), the Federal Trade Commission Act, 15 U.S.C. § 42, *et seq.* ("FTC Act"), and some provisions of California's Health & Safety Code. Hansen moved to dismiss.

Confronted with overwhelming federal authority that it had no standing to assert claims for the enforcement of remedies exclusively within the jurisdiction of the Food and Drug Administration ("FDA") and/or the Federal Trade Commission ("FTC"), Living Essentials filed its amended counterclaim. Living Essentials has, however, simply substituted provisions of California's Health & Safety Code ("California's Sherman Law") for some, but not all, of the previously cited sections of the FDCA and FTC Act.[1] The substantive allegations of the amended counterclaim remain almost **verbatim** the allegations in the original counterclaim.[2] As a consequence, Living Essentials may not masquerade behind California's Sherman Law or Bus. & Prof. Code §§ 17200 and 17500 to attempt to enforce the FDCA or FDA regulations.

II
BRIEF PROCEDURAL HISTORY

Original Complaint.

On July 1, 2008, Hansen filed this Lanham Act case against Living Essentials because of its false and misleading advertising about its 2-oz. energy shot product, 5-Hour Energy®, and also because of its false claims about Hansen's Monster Energy® drink products.

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[1] Living Essentials still relies on the FDCA, 21 U.S.C. § 343(a), for its allegation that Hansen's labeling is deceptive with respect to serving size, calorie, carbohydrate and sugar listing (amended counterclaim ¶ 45) and on "federal labeling laws" with respect to alleged misbranding as a dietary supplement (*Id.* ¶ 57).

[2] For the Court's convenience, Hansen lodges as Exhibit 1, a Word "red line" comparison of the original and amended counterclaims. McIntyre Declaration, Exhibit 1.

Amended Complaint.

Then, after Living Essentials aired two new, defamatory commercials that directly and falsely attacked and disparaged Hansen's Monster Energy® drink products, on August 11, 2009, Hansen amended its complaint. (Doc. No. 97). That amendment, however, changed nothing except to add the text of those two commercials (¶¶ 27 and 29), and a short statement how each is false and misleading (¶¶ 28, 30). The thrust of the amended complaint remained the same.

Original Counterclaim and Motion to Dismiss.

On August 27, 2009, Living Essentials filed its original counterclaim (Doc. No. 106). On September 16, 2009, Hansen filed a motion to dismiss, citing incontrovertable federal authority that Living Essentials had no standing for its patent attempt to bring a private action under the FDCA and FTC Act (Doc. No. 111).

Amended Counterclaim.

On October 12, 2009, Living Essentials filed its amended counterclaim that merely substituted provisions of California's Sherman Law for the previously cited sections of the FDCA and FTC Act. That substitution fails. Living Essentials relies on the *Farm Raised Salmon Cases*, 42 Cal.4th 1077 (2008) ("*Farm Raised*") as its sole authority to attempt to back door, under California's Sherman Law, what federal courts have consistently said it cannot do—attempt to enforce the FDCA through a private action. Living Essentials' thinly disguised attempt to circumvent decades of federal law fails and its amended counterclaim should be dismissed.

III
THE FEDERAL STATUTES AT ISSUE

The FDCA unequivocally identifies the only parties that have standing to enforce its provisions. The FDCA, 21 U.S.C. §§ 337, provides, in relevant part:

> (a) Except as provided under subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.....
>
> (b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(1), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)-

> (A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,
>
> (B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or
>
> (C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.[3]

As amended in 1990, FDCA further provides, 21 U.S.C. § 343-1, in relevant part:

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce –

> (1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(q) …,
>
> (2) any requirement for the labeling of food of the type required by section 403(c), 403(e), 403(i)(2), 403(w), or 403(x) that is not identical to the requirement of such section …,
>
> (3) any requirement for the labeling of food of the type required by section 403(b) 403(d), 403(f), 403(h), 403(i)(1), or 403(k) that is not identical to the requirement of this section …,
>
> (4) any requirement for nutritional labeling of food that is not identical to the requirement of section 403(q), except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 403(q)(5)(A) or,
>
> (5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not identical to the requirement of section 403(r), except a requirement respecting a claim made in the label or labeling of food which is exempt under section 403(r)(5)(B).

Thus, when Congress enacted the FDCA in 1938, it deliberately and consciously rejected the possibility of private enforcement in favor of **exclusive** federal jurisdiction. When Congress amended the Act in 1990, it carved out a limited exception to exclusive federal enforcement, allowing state governments to enforce certain FDCA provisions, but under specified conditions.

[3] Congress added § (b), giving states limited enforcement authority by a 1990 amendment.

As the statute itself demonstrates, Congress never altered its long-standing prohibition against private enforcement actions.

IV
FARM RAISED DOES NOT SUPPORT LIVING ESSENTIALS' AMENDED COUNTERCLAIM

Farm Raised provides no support for Living Essentials' attempt to claim a private right of action to pursue its amended counterclaim. *Farm Raised* acknowledged that the FDCA's 1990 amendment (21 U.S.C. § 343-1) prohibits the states from, directly or indirectly, establishing food labeling requirements that are "**not identical**" to specific, enumerated provisions of the FDCA. *Farm Raised, supra*, at 1086. From that negative prescription, *Farm Raised* infers that states may then establish labeling requirements that are "**identical to**" those in the FDCA. *Id.* at 1086.

The only issue in *Farm Raised* was the use, without disclosure, of astaxanthin and canthaxanthian as color additives "to enhance the pink or orange-red color of the flesh of salmonid fish." *Id.* at 1085. FDA regulation permits use of those chemicals (21 C.F.R. §§ 73.35(c) and 73.75(c)(3)), **but** the chemical must be disclosed (21 C.F.R. §§ 73.35(d)(3) and 73.75(d)(4)).

Accordingly, *Farm Raised* found that California's Sherman Law (Health & Saf. Code, § 110740) "uses language '**identical to**' section 343(k), which provides that food is misbranded "if it bears or contains any … artificial coloring … unless its labeling states that fact."[4] *Id.* at 1086, emphasis added.

Because that specific provision of California's Sherman Law (§ 110740) is **identical** to FDCA § 343(k), *Farm Raised* concluded that that single provision met the requirement specifically listed in § 343-1 and thus escaped federal preemption. *Id.* at 1090. Concluding that the specific provision at issue was not preempted, *Farm Raised* then took the next step—private enforcement.

The court admitted that absolutely nothing in the 1990 amendment permitted a private right of action to enforce state provisions identical to the specifically enumerated provisions of § 343-1. *Id.* at 1090. The court found such a private right of action, however, only because

[4] Subsequent citations to California's Sherman Law are to the Health & Safety Code.

nothing in the 1990 amendment **prohibited** it and because the plaintiffs' claims for deceptive marketing of food products were predicated on state law "**identical to**" the disclosure requirements imposed by the FDCA, § 343-1(a)(3). *Id.* at 1098-99. Whether *Farm Raised* properly interprets and applies **federal** law is discussed at length below.[5]

The *Farm Raised* "exception," however, to the absolute prohibition of 21 U.S.C. § 337 (enforcement only by the United States and, in limited circumstances, states) does not support Living Essentials' claimed private right of action. With but one possible exception discussed below,[6] the sections of California's Sherman Law that the amended counterclaim specifically pleads are **not identical** to enumerated provisions in 21 U.S.C. § 343-1.[7] Thus, *Farm Raised* offers no support for the amended counterclaim.

For the Court's convenience, Hansen has prepared a chart of the provisions of California's Sherman Law on which Living Essentials relies.[8] As that chart illustrates, with the one exception mentioned, **no** provision on which Living Essentials relies is "**identical to**" the permissible, enumerated provisions of 21 U.S.C. § 343-1. Thus, whether *Farm Raised* correctly or incorrectly found a private right of action to enforce provisions of California's Sherman Law "identical to" the enumerated provisions in the 1990 FDCA amendment, Living Essentials has, with one exception, pled **no** such "identical" provision. Accordingly, even *Farm Raised* does not support this private enforcement action that Living Essentials' amended counterclaim attempts.

V
LIVING ESSENTIALS HAS NO STANDING TO ENFORCE EITHER THE FDCA OR ANY FDA REGULATION

Precisely because one provision of California's Sherman Law (§ 110670) finds, but only by incorporation, a parallel in 21 U.S.C. § 343(r), and also because California's Sherman Law purports to adopt wholesale (§ 110100(a)) **all** FDA food labeling regulations and (§ 110505) the

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5 See pp. 14-20.

6 Section 110670 merely incorporates by reference § 21 U.S.C. § 343(r). Whether that incorporation is sufficient to be "identical to" is unimportant. That incorporation by reference defeats a private right of action precisely because of the FDA's primary jurisdiction. See cases discussed below at pp. 5-13.

7 See amended counterclaim ¶¶ 17-57, pleading California's Sherman Law, §§ 109940, 110100(a), 110290, 110390, 110398, 110445, 110505, 110555, 110655, 110660.

8 McIntyre Declaration, Exhibit 2.

definitions of 21 U.S.C. § 341, Living Essentials has no standing to pursue enforcement of that section or those regulations by a private action.

Federal courts have steadfastly dismissed Lanham Act—and any parallel state law—claims that necessarily require interpretation and/or application of the FDCA or FDA regulations—precisely what Living Essentials would have this Court do. *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230-31 (3d Cir. 1990) ("[W]hat the [FDCA] ... do[es] not create directly, the Lanham Act does not create indirectly"); *Rita Med. Sys., Inc. v. Resect Med., Inc.*, 2006 U.S. Dist. LEXIS 52366, at *10 (N.D. Cal. July 17, 2006) ("Lanham Act cannot be used as a circuitous route to challenge determinations of the FDA").

Decisions Within This District.

Just recently, Judge Moskowitz dismissed state law unfair competition claims—Civ. Code § 1750 and Bus. & Prof. Code § 17200—alleging "adulteration" within the meaning of the FDCA and violations of an FDA regulation (21 C.F.R. § 1040.10). The court held that plaintiffs' claims would:

> [R]equire the Court to make determinations regarding the scope of the [FDA premarket approval (21 U.S.C. § 360e(a))], whether the modified Lasers were "adulterated" under section 501(f)(1)(B) of the FDCA, and whether re-certification was required under 21 C.F.R. § 1040.10. These matters should be decided by the FDA in the first instance.... The Court will not permit Plaintiffs to privately enforce the FDCA and its regulations under the guise of state law claims.

Perez v. Nidek Co. Ltd., 2009 U.S. Dist. LEXIS 78214, at *21 (S.D. Cal. Aug. 31, 2009).

The rationale Judge Moskowitz applied, and the authorities on which he relied, drive the same conclusion here. Living Essentials cannot, under the guise of California's Sherman Law with its incorporation by reference of a single FDCA provision, 21 U.S.C. § 343(r), and **all** FDA food labeling regulations and, obliquely, § 341's definitions,[9] privately enforce that FDCA provision or those FDA regulations or definitions concerning alleged "adulteration," "misbranding," or whether Hansen's products constitute dietary supplements—subject to one kind

[9] See §§ 110100 and 110505.

of regulation—or conventional foods—subject to another.[10] That is for the FDA, not the federal courts—as so many federal courts have held.

In *Photomedex, Inc. v. RA Medical Systems Inc.*, 2007 U.S. Dist. LEXIS 79846 (S.D. Cal. Oct. 29, 2007) (Sammartino, J.), the court dismissed plaintiff's claims under the Lanham Act and Bus. & Prof. Code §§ 17200 and 17500 precisely because they depended on whether design changes defendants made to their laser required additional filings with the FDA to obtain further pre-market clearance. The court held that the determination whether the defendants were improperly marketing a laser that was not FDA-approved required application of FDA regulations and FDA expertise. *Id.* at *9.

In another case in this District, *Fraker v. KFC Corp.*, 2007 U.S. Dist. LEXIS 32041 (S.D. Cal. Apr. 27, 2007) (Miller, J.), the court held:

> Here, as instructed in *Buckman*, the FDCA presents a comprehensive regulatory scheme of branding and labeling of food products. To overlay the state law tort system over the FDCA would significantly increase the burdens on the FDA to ensure uniform enforcement of its administrative duties. Accordingly, to the extent Plaintiff contends that alleged violations of the FDCA and Sherman Law give rise to viable state law claims, such claims are impliedly preempted by the FDCA.

Id. at *10-11. *See also Cox v. Depuy Motech, Inc.*, 2000 U.S. Dist. LEXIS 22849, at *25 (S.D. Cal. Mar. 29, 2000) (Lorenz, J.) and *Little v. Depuy Motech, Inc.*, 2000 U.S. Dist. LEXIS 22698, at *25 (S.D. Cal. June 9, 2000) (Lorenz, J.) (*citing Summit Tech. v. High-Line Med. Instruments Co., Inc.*, 922 F. Supp. 299 (C.D. Cal. 1996) (Summit I)) ("The FDCA and the MDA do not provide a private cause of action.").

Decisions of the Ninth Circuit and Other Courts Within This Circuit.

Both the Ninth Circuit and other district courts within this Circuit have reached the same conclusion for the same reasons.

In *Fiedler v. Clark*, 714 F.2d 77, 79 (9th Cir. 1983), the court affirmed a dismissal for lack of subject matter jurisdiction because Fiedler was a private party suing in his own name; the court had no jurisdiction under the FDCA, 21 U.S.C. § 337.

[10] See counterclaim ¶¶ 17-57.

Likewise, in *Infa-Lab, Inc. v. KDS Nail Int'l.*, 2009 U.S. Dist. LEXIS 4509 (E.D. Cal. Jan. 21, 2009), the court granted summary judgment because the plaintiff's state law claims were squarely premised on violations of FDA regulations and provisions of the FDCA.

> Because these claims are "merely vehicles for claims under the FDCA or FDA regulations," their adjudication "would force the [c]ourt to rule directly on the legality of [defendant's] conduct before the FDA has had a chance to do so." This the court cannot do.

Id. at *11 (*citing Summit Tech, Inc. v. High-Line Med. Instruments Co.*, 933 F. Supp. 918, 943 n.21 (C.D. Cal. 1996) (Summit II)) ("[A] plaintiff may not bring a section 17200 claim that is, in fact, an attempt to state a claim under the federal FDCA.").

In *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008), the court dismissed plaintiffs' RICO and Bus. & Prof. Code § 17200 claims because they were primarily based on allegations that the defendants promoted a prescription drug for off-label uses, causing the drug to be "misbranded" in violation of the FDCA. The court found that plaintiffs' suit was largely an attempt to bring a private cause of action for violation of the FDCA and FDA regulations that prohibit drug manufacturers from promoting off-label uses of prescription drugs. The court dismissed the complaint. ("[W]hat the FDCA does not create directly, RICO cannot create indirectly." *Id.* at 1290 (*citing Sandoz Pharm.*, 902 F.2d at 231); *see also, Leblanc Nutrition, Inc. v. Advanced Nutrition, LLC*, 2005 U.S. Dist. LEXIS 45500, at *14 (E.D. Cal. June 14, 2005) ("As a private party, plaintiff cannot maintain an action under the FDCA.").

In *Summit I*, the plaintiff attempted to assert a Lanham Act claim based on the defendants' alleged failure to disclose that their re-imported excimer laser systems were materially different from the FDA-approved systems and were not themselves FDA-approved. The court dismissed the Lanham Act claim. Because the FDA had not completed its investigation whether the defendants had violated FDA regulations by marketing the re-imported machines, plaintiff's claim would have required the court to usurp the FDA's authority to enforce the FDCA:

> A Lanham Act cause of action cannot stand if it alleges that a defendant has failed to disclose the *fact* of FDA non-approval, when the FDA has not yet determined whether or not the product in question has been approved. Simply put, the Lanham

Act does not allow a federal court to "determine preemptively how a federal agency will interpret and enforce its own regulations."

Id. at 306 (*quoting Sandoz Pharm.*, 902 F.2d at 223) (emphasis in original); *see also Ginochio v. Surgikos, Inc.*, 864 F. Supp. 948, 956-57 (N.D. Cal. 1994) (granting summary judgment on causes of action alleging that defendants failed to comply with the FDCA or FDA regulations specifically performance standards for artificial knee implants).

Other Federal Courts.

Beyond this circuit, federal courts have interpreted Section 337(a)—"all such proceedings for the enforcement, or to restrain violations of [the Act] shall be by and in the name of the United States"—that **no** private right of action exists to redress alleged violations of the FDCA. *See, e.g., Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994); *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993); *Sandoz, supra*, 902 F.2d 222; *Pacific Trading Co. v. Wilson & Co., Inc.*, 547 F.2d 367, 370 (7th Cir. 1975) ("Violations of the FDCA do not create private rights of action.").

In *Sandoz*, 902 F.2d 222, the plaintiff claimed that the defendant violated the Lanham Act because its labels were literally false, alleging that the defendant listed an ingredient as "inactive" when it was "active" under FDA regulation. To determine whether this characterization was literally false, the trial court would have had to interpret that FDA regulation and, accordingly, it dismissed the plaintiff's claims. *Id.* at 231. The Third Circuit affirmed. The court explained that the FDA had not yet found conclusively whether demulcents must be labeled as "active" within the meaning of 21 C.F.R. § 210.3(b)(7) and that it was not proper for a district court to "usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations." *Id.* at 231.

In *Autin v. Solvay Pharmaceuticals, Inc.*, 2006 U.S. Dist. LEXIS 19507, at *11 (W.D. Tenn. Mar. 31, 2006), the court held that § 337(a) preempts state law claims "based on an alleged violation of the FDCA;" *see also Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002) (courts should not usurp the FDA's authority to interpret and enforce its own regulations). And in *Anthony v. Country Life Mfg., L.L.C.*, 2002 U.S. Dist. LEXIS 19445,

at *3 (N.D. Ill. Oct. 7, 2002), the court granted defendant's motion to dismiss state consumer fraud claims on the ground that they "amount[ed] to nothing other than an attempt to enforce the FDCA."

In *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 837 (W.D. Tex. 2001),in dismissing defendant's false advertising counterclaim where the "touchstone" of defendant's argument was an FDCA violation, the court stated: "[T]he District Court should not 'determine preemptively how a federal agency will interpret and enforce its own regulations.'"

In *Braintree Laboratories., Inc. v. Nephro-Tech, Inc.*, 1997 U.S. Dist. LEXIS 2372 (D. Kan. Feb. 26, 1997), the court dismissed Lanham Act and common law unfair competition claims because their crux was that defendants had failed to receive FDA approval for a "dietary supplement," resulting in alleged misbranding under the FDCA. The Court said:

> [I]t is not for this court to interpret and apply the statutory definition of "dietary supplement." In particular, the court notes that under the FDCA, a product is misbranded if it is a "dietary supplement" under the FDCA and that term is not used on its label.

Id. at *21. As a consequence, the court held that the misbranding claim must be reserved solely for resolution by the FDA. *Id. Braintree Laboratories* is directly on point. In its amended counterclaim, Living Essentials claims that Hansen's products are misbranded as "dietary supplements."[11] For reasons the same as *Braintree Laboratories*, this Court should defer to the FDA and dismiss Living Essentials' amended counterclaim.

Accordingly, federal courts have steadfastly held that where a claim, whether premised on the Lanham Act or some state statute, would require the court to interpret a FDA regulation, prejudge what the FDA will do, or otherwise to interfere with the FDA's primary jurisdiction, there is no private right of action.

The Amended Counterclaim's Charging Allegations Are Conclusive.

The amended counterclaim's charging allegations (from ¶ 17 to ¶ 57) underscore that it would enmesh this Court in FDA regulations.

[11] See amended counterclaim ¶¶ 12 and 51-57.

Paragraphs 17-31.

Paragraphs 17 through 31 allege that Hansen promotes 18 of its products[12] to achieve intoxication either through excessive caffeine or by mixing the products with alcohol. Living Essentials alleges that this presents "a significant or unreasonable risk of illness or injury" such that the products are "adulterated" and unlawful to sell under California's Sherman Act (§ 110100(a)—adopting **all** FDA food labeling regulations—and also §§ 109940, 110445, 110555, 110745). Living Essentials had previously alleged these same "facts" violated 21 U.S.C. § 342(f)(1), 21 U.S.C. § 331(a) and 348(a), and 21 C.F.R. § 182.1180(c).

These allegations grossly misconstrue the statutory scheme governing the regulation of dietary supplements and food additives, and seek relief from this Court that would run counter to the FDA's own implementation of provisions of the FDCA. The FDA has never regulated what consumers may do with food products once purchased. Rather, the agency regulates manufacturers of foods and dietary supplements, including what they may use in formulating the products they sell. Food additives, as defined at 21 U.S.C. § 321(s), are substances that are intended to become a component of food, "including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food." It is clear from this definition, as well as from the FDA's food additive regulations, codified at 21 C.F.R. §§ 172-180, that food additives are substances that manufacturers use in **making** their products. Finished products such as Hansen's dietary supplements are **not** food additives and the FDA does not treat them as such. A consumer's "addition" of these products to other foods or beverages does not make Hansen's products "food additives" under the FDCA.[13]

Similarly, the adulteration provisions of the FDCA do not apply to a consumer's mixing foods or dietary supplements with other substances or to a consumer's use of a safe product in a harmful manner. A consumer's use of a food or dietary supplement cannot render the product

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[12] The 11 that Living Essentials calls "Hansen Energy Beverages" (amended counterclaim, 30:17-21) and the 7 that Living Essentials calls "Monster Energy Coffees" (amended counterclaim, 30:23-31:1).

[13] Living Essentials would presumably outlaw "Irish Coffee" as "misbranded" or "adulterated" and put the venerable Buena Vista out of business.

"adulterated" under the FDCA or FDA regulations. Living Essentials does **not** allege that any Hansen product, standing alone, presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in its labeling (§ 342(f)(1)(A)(i)), or that it is a new dietary ingredient for which there is inadequate information reasonably to insure that it does not present such a risk (§ 342(f)(1)(A)(i) or (B)).

In sum, adjudicating Living Essentials' amended counterclaim, paragraphs 17 through 31, would require this Court to interpret the scope of the FDCA and FDA's implementing regulations. Worse, to provide the relief Living Essentials seeks, the Court would need to interpret these provisions in a manner contrary to the established statutory and regulatory scheme. Living Essentials cannot have this Court craft novel interpretations of the FDCA or FDA regulations under state law claims when Congress has established and empowered the FDA as the agency to regulate those very products.

Paragraphs 32-33.

Paragraphs 32 and 33 rely on California's Sherman Law (§§ 110390; 110398; 110290; 110555; 110660; 110655; and 110745) none of which is "**identical to**" any enumerated provision of § 343-1. Thus, they are beyond even *Farm Raised.* In addition, because § 110655 directly implicates the FDCA, adjudication of these claims would require this Court's interpretation of 21 U.S.C. §§ 342(f)(1) and 321(ff)(2)(B) and 343(a) and determinations about their scope and whether the alleged advertising causes these products to be "misbranded" under federal law.

Paragraphs 34-45.

Paragraphs 34 through 45 attack the "two servings" statement on the Hansen products that come in 15 and 16 ounce containers. Living Essentials contends, *inter alia*, that these products are intended to be consumed in a single sitting, and, thus, that the Supplemental Facts, based on an 8-ounce serving, are false. Living Essentials relies, *inter alia*, on 21 U.S.C. § 343(a) and California's Sherman Law (§§ 110290, 110505, 110655, 110660, and 110670). Section 110670 expressly requires interpretation of 21 U.S.C. § 343(r) and all regulations adopted pursuant to it.

The FDA has promulgated extensive requirements for listing serving size—21 C.F.R. § 101.9(b)(2), 21 C.F.R. § 101.12(b) (Table 2), 21 C.F.R. § 101.9(b)(8)(i), 21 C.F.R.

§ 101.30(b)(1). In spite of these regulations, Living Essentials would have this Court determine the size of the print of the "2 servings" on the Hansen label and also whether a 16-ounce can properly contains two 8-ounce servings even if it cannot be resealed. Any such determination is within the province of the FDA and Living Essentials cannot interject it here.

Paragraphs 46-50.

Paragraphs 46 through 50 originally purported to raise claims under 15 U.S.C. § 45(a) and 15 U.S.C. § 52(a)-(b) which a private party cannot assert. *See Carlson v. The Coca-Cola Co.*, 483 F.2d 279, 280-81 (9th Cir. 1973); *Washington v. United States Tennis Ass'n.*, 290 F. Supp. 2d 323, 328 (E.D. N.Y. 2003). Now Living Essentials substitutes two provisions of California's Sherman Law (§§ 110290 and 110390), which have no enumerated counterpart in 21 U.S.C. § 343-1. Adjudication, however, would require this Court's interpretation of 21 U.S.C. §§ 342(f)(1) and 321(ff)(2)(B) and 343(a) and determinations about their scope and whether the alleged advertising causes these products to be "misbranded" under **federal** law.

Paragraphs 51-57.

Paragraphs 51 through 57 contend that Hansen's products are not proper dietary supplements but rather conventional foods. Living Essentials specifically relies on **federal law** (¶¶ 52 and 57). Thus Living Essentials would have this Court determine whether Hansen products are misbranded under 21 U.S.C. § 321(ff)(2)(B) and 21 U.S.C. § 343(a). The FDA, however, has exclusive jurisdiction over the application of the dietary supplement classification and the administrative expertise to make those determinations. *See Braintree Lab., supra,* at *21. These issues are not properly before this Court; they belong with the FDA.

The Whole of the Amended Counterclaim is Beyond This Court's Jurisdiction.

Thus, all of the charging allegations in Living Essentials' amended counterclaim are within the exclusive jurisdiction of the FDA and would require this Court either to anticipate how the FDA would rule on them or to contradict established FDA precedent. Because federal courts have dismissed other attempts to do the same thing and deferred to the FDA's expertise, there is little or no judicial guidance interpreting these FDA regulations.

Living Essentials cannot assert these FDA-based charges in this private action. As a result,

Living Essentials' amended counterclaim must be dismissed, with prejudice, as a matter of law.

VI
FEDERAL COURTS, NOT STATE COURTS, HAVE THE LAST WORD ON ISSUES OF FEDERAL LAW

Living Essentials cannot dispute that the issue of federal preemption poses a question of federal law. *Local Union 598 v. J.A. Jones Constr. Co.*, 846 F.2d 1213, 1218 (9th Cir. 1988). Accordingly, the holding in *Farm Raised* has no effect here. In *Fraker, supra*, after Judge Miller dismissed state law claims based on alleged violations of the FDCA and §§ 17200 and 17500, the court then declined to stay that dismissal to wait for *Farm Raised*:

> The court declines to stay the present action because Plaintiff fails to establish exceptional circumstances warranting the requested relief. **The California Supreme Court's decision on the question of federal preemption is not binding on this court.** As explained in [citation omitted], a stay under *Colorado River* is only appropriate if the parallel state-court litigation "will be an adequate vehicle for the complete and prompt resolution of the issues." Here, a resolution of the *In re Farm Raised Salmon Cases* **will not resolve the preemption issue as this court is not bound to follow the California Supreme Court on any issue of federal law.** Consequently, the court declines to stay this action.

Fraker, supra, at *12-13(emphasis added).

Fraker is simply a recent reiteration of a long-standing principle of federal jurisprudence: state courts do not bind federal courts on issues of federal law. Indeed, the opposite is the case. *See, Fiedler, supra*, at 78 ("[T]he states have no power directly to enlarge or contract federal jurisdiction," affirming dismissal of a private action alleging, *inter alia*, violations of FDCA). *See also Lewis v. United States*, 200 F.2d 183, 186 (9th Cir. 1952) ("Where, as in this case, Congress has authorized a public officer to condemn the fee title, a state's declaration of substantive law or policy to the contrary is not controlling."); *U.S. v. Montana*, 134 F.2d 194, 196 (9th Cir. 1943) (A state supreme court's "interpretation of the federal statute, is, of course, not binding on the federal courts"); *Rush v. Obledo*, 517 F. Supp. 905, 911 (N.D. Cal. 1981) ("This court is not bound by ... a California state court's interpretation of federal law.").

Other circuit courts agree. *See Wojchowski v. Daines*, 498 F.3d 99, 110 n.9 (2d Cir. 2007) ("We are, of course, not bound by a state court's interpretation of federal law."); *First American Title Co. v. DeVaugh*, 480 F.3d 438, 455 (6th Cir. 2007) ("A state court's opinion on an issue of federal law ... is entitled to no deference whatsoever."); *Barton v. County of Denver*, 2007 U.S.

App. LEXIS 24940, at *4 (10th Cir. Oct. 24, 2007) ("[T]he stare decisis effect of a state court decision interpreting federal law is limited to the courts of that state; that doctrine cannot bind a federal court to follow a state court's interpretation of federal law"); *Surrick v. Killion*, 449 F.3d 520, 535 (3d Cir. 2006) ("decisions of the Pennsylvania Supreme Court do not bind this Court with respect to federal law"); *Hawkman v. Parratt*, 661 F.2d 1161, 1166 (8th Cir. 1981) ("the federal courts need not defer to a state court's interpretation of federal law"); *United States of America v. Bedford*, 519 F.2d 650, 654 (3d Cir. 1975) ("It is a recognized principle that a federal court is not bound by a state court's interpretation of federal laws or of a state statute under misapprehension of federal law."); *see also, Martin v. Hunter's Lessee*, 14 U.S. 304 (1816).

As a consequence, not only is this Court not bound by *Farm Raised*, but this Court should reject it precisely because *Farm Raised* departed from both the express intent of Congress and more than fifty years of federal jurisprudence.

VII
FARM RAISED SALMON CONFLICTS WITH CONGRESS' PROHIBITION AGAINST PRIVATE FDCA ENFORCEMENT AND COURT DECISIONS UPHOLDING THAT PROHIBITION

"'Preemption is always a matter of congressional intent.' 'Since the existence of preemption turns on Congress's intent, we are to 'begin as we do in any exercise of statutory construction[,] with the text of the provision in question, and move on, as need be, to the structure and purpose of the Act in which it occurs.'" *In re Pepsico, Inc.*, 588 F. Supp. 2d 527, 530 (S.D. N.Y. 2008) (internal citations omitted). In determining Congressional intent to preempt state law, federal courts apply the following analytical framework:

> If the statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent. Where the language of the statute plainly indicates that Congress intended preemption, we must give effect to the plain language unless there is good reason to believe Congress intended the language to have some more restrictive meaning. If the text of the statute is ambiguous, either as to Congress's intent to preempt at all or as to the extent of an intended preemption, the meaning of the statute may be gleaned from its context and from the statutory scheme as a whole, or by resort to the normal canons of construction and legislative history.

Id. at 530-31 (internal citations omitted).

Section 337 Reflects Congress' Unmistakable Intent To Preclude Private Enforcement.

The Original FDCA § 337.

Section 337 originally mandated that **only** the federal government could enforce the Act (21 U.S.C. § 337(a)). All courts interpreting the FDCA's enforcement framework, and specifically § 337 before it was amended in 1990, held that Congress had deliberately excluded private claims by placing enforcement exclusively in the hands of the federal government. *See, e.g., Pacific Trading Co. v. Wilson & Co., Inc.*, 547 F.2d 367, 370 (7th Cir. 1976) ("[T]he statute does not provide a cause of action for private parties suing for civil damages."). That included claims brought under state law. *See, e.g., National Women's Health Network, Inc. v. A. H. Robins Co.*, 545 F. Supp. 1177, 1181 (D. Mass. 1982) (holding that a private right of action to enforce FDCA standards is "inconsistent with the federal regulatory scheme, whether the right is based in federal or state law"); *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 283 (D. Mass. 1986) (same).

FDCA § 337, As Amended.

When Congress amended § 337 in 1990 to allow certain **limited** actions by **state** governments, it was obviously aware of that uniform case law. *Keene Corp. v. United States*, 508 U.S. 200, 212 (1993) (when Congress reenacts statutory language that has been consistently interpreted by the courts, "the presumption that Congress was aware of the earlier judicial interpretations and, in effect, adopted them" applies).

Thus, while Congress expressly authorized limited **state** enforcement, it made no change in the proscription against private enforcement under § 337. *Bailey v. Johnson*, 48 F.3d 965, 967 n.1 (6th Cir. 1995) (dismissing a private cause of action to enforce the FDCA, the court said that, when Congress amended § 337 to allow for certain state enforcement actions, it "made no change respecting private actions").

More importantly, the United States Supreme Court held in 2001 that "[the FDCA leaves no doubt" that "private litigants" cannot bring suits for noncompliance with the FDCA. *Buckman Company v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Federal appellate courts agree. See, e.g., *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788 (3d Cir.

1999) ("It is well-settled ... that the FDCA creates no private right of action."); *PDF Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (holding that "no ... private right of action exists" under the FDCA); *Bailey*, 48 F.3d at 968 ("Congress did not intend, either expressly or **by implication**, to create a private cause of action under the FDCA" (emphasis added)).

Section 343-1 Did Not Alter Congress' Longstanding Ban On Private Enforcement Actions.

When Congress did not prohibit states from enacting laws "**identical to**" enumerated federal labeling requirements, it was legislating in an area that included its own more than fifty-year ban on private enforcement. Thus, any argument that Congress **silently** obliterated its half-century regime of exclusive government enforcement is untenable. In 1990, Congress allowed state governments—the same parties that 21 U.S.C. § 337(b) simultaneously permitted to bring certain enforcement actions—to enforce the specific provisions of § 343-1. Absolutely nothing in § 343-1, however, suggests that Congress ever intended to allow private enforcement.

The Federal Statutory Scheme Precludes Any Private Right of Action.

Congress' Original Plan Mandated Exclusive Federal Enforcement and Unequivocally Prohibited Private Enforcement.

From its inception in 1938, the FDCA was intended to be enforced by the federal government—not by private parties. In fact, Congress considered and rejected a version of the statute that would have allowed a private right of action. *National Women's Health Network, supra*, at 1179-80 (citing Hearings on S. 1944 (Subcommittee of Committee on Commerce 73d Cong., 2d Sess. (1933)). It opted instead for a provision mandating that "all" proceedings "for the enforcement, or to restrain violations" of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337.

In keeping with its plan of exclusive federal enforcement, Congress gave the FDA, the responsible federal agency, a wide range of enforcement options. It authorized the FDA to bring civil actions to seize misbranded or adulterated goods, to restrain violations of the FDCA, and to seek civil and criminal penalties for such violations. 21 U.S.C. §§ 332-334. As part of its careful statutory and regulatory design, Congress also gave the FDA the power **not** to prosecute "minor violations of [the Act] whenever [it] believes that the public interest will be adequately served by a

suitable written notice or warning." 21 U.S.C. § 336. Congress thus ensured that the federal government would decide whether and how to enforce the law.

The 1990 Amendments Created A Limited Role For The States, But None For Private Parties.

Cognizant of the uniform case law prohibiting private enforcement, Congress enacted the Nutrition Labeling and Education Act of 1990 ("NLEA"), two provisions of which address state enforcement of federal labeling requirements: §§ 343-1 and 337(b).

Section 343-1 does not prohibit regulation "**identical to**" certain FDCA labeling requirements. 21 U.S.C. §343-1. Although § 343-1 is silent on the issue of enforcement, the House Report is unequivocal that any state law enacted pursuant to § 343-1 may only be enforced by "governmental entities:"

> The bill ... contains a provision that would prevent State and local governments from adopting inconsistent requirements with respect to the labeling of nutrients or with respect to the claims that may be made about the nutrients in foods. However, these **governmental entities are explicitly permitted to enforce Federal requirements with respect to nutrition labeling**.

(H.R. Rep. No. 101-538, 2d Sess., p. 8 (1990) (emphasis added).)

The other amendment was the addition of § 337(b) to the original § 337. It carved out a narrow exception to exclusive federal enforcement, but, again, **only** for the states. Section 337(b) permits state enforcement of certain sections of the FDCA, but only after the state gives the FDA notice and the opportunity to preempt state government action with an action of its own. 21 U.S.C. § 337(b).

As Representative Henry Waxman, who originally introduced the bill in the House, explained:

> HR. 3562 recognizes the importance of the **State role**: by allowing **States** to adopt standards that are identical to the Federal standard, which may be enforced in State court; by allowing the **States** to enforce the Federal standard in Federal court.

(House Debate on H.R. No. 3562, 101st Cong., 2d Sess., 136 Cong. Rec. 1539 (daily ed. July 30, 1990) (emphasis added).) Thus, §§ 337(b) and 343-1 allowed **state** enforcement of certain federal labeling requirements, but **never** gave private parties any enforcement rights whatsoever.

The *Farm Raised* Court's Rationale.

Farm Raised court largely justifies its conclusion by pointing to FDCA § 343-1, from which it inferred that states could adopt laws **identical to** certain federal labeling requirements. Acknowledging that Congress "said absolutely nothing" about private enforcement when enacting § 343-1, the court nevertheless **presumed** that Congress "did not intend to alter the *status quo*, i.e., states may choose to permit their residents to file unfair competition or other claims based on the violation of state laws," including state laws identical to the limited provisions of § 343. *Farm Raised* at 1091. *Farm Raised*, however, fails to acknowledge that the "*status quo*" was Congress' longstanding **ban** on private enforcement actions in FDCA § 337, a statutory mandate born of Congress' decision to reject a version that would have allowed a private right of action (*see National Women's Health, supra*, at 1179-80) and intended to exclude private litigants from the Act's enforcement scheme (*Buckman*, 531 U.S. at 349 n.4).

When *Farm Raised* insisted that FDCA § 337 "only implicates efforts to enforce federal law," and does not "limit, prohibit, or affect private claims predicated on state laws," it simply ignored the fact that, when Congress amended § 337 in 1990, it knew that the provision had been consistently interpreted to preclude private actions brought under both federal and state law. Had Congress intended to allow private state law actions, section 343-1 presented the perfect—and perhaps necessary—opportunity. While not prohibiting states from enacting, or even permitting states to enact, laws **identical** to certain FDCA provisions, Congress could easily—and perhaps should—have told the courts that—contrary to what they had held for decades—private actions to enforce state replicas of FDCA provisions would, therefore, be allowed. It pointedly did not.

Contrary to *Farm Raised's* presumption, Congress gave not even a hint that it intended to authorize private enforcement when it enacted an unambiguous, highly detailed provision for **state** enforcement. No one can credibly argue that when Congress changed the law with respect to **state** enforcement, it actually, but silently, intended to permit both state and **private** enforcement. See *Monessen Southwestern Ry. Co. v. Morgan*, 486 U.S. 330, 336-38 (1988) (where Congress had amended a statute and "dispensed with [certain] doctrines," but had not addressed the specific doctrine at issue, the Supreme Court has considered "Congress' silence on this matter in the

appropriate historical context" and was "unpersuaded that Congress intended to abrogate that doctrine *sub silentio*").

The legislative history, which discusses the "importance of the state role" and refers to enforcement by "governmental entities," makes the *Farm Raised* theory that Congress somehow intended to allow private enforcement without ever mentioning it even more implausible. It is inconceivable that Congress, by its silence, changed the law to allow private enforcement of state laws identical to the FDCA—when it had consistently and unequivocally prohibited such private enforcement of the federal law itself. As the Sixth Circuit recognized in *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995), a private cause of action under the FDCA would jeopardize the "major advantages" of government enforcement, "including expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a uniform enforcement policy."

Thus, *Farm Raised* would undermine federal and state governments' ability to enforce federal labeling requirements "consistently with [their] judgment and objectives." *Buckman*, 531 U.S. at 350. Permitting private parties to enforce the FDCA and identical state statutes only frustrates Congress' intent to keep enforcement in the hands of experienced government entities capable of coordinating their enforcement efforts. *Farm Raised* flies in the face of the express language of the federal statute, its Legislative history and more than five decades of federal jurisprudence. This Court can, and should, disregard *Farm Raised's* interpretation of this federal statute and its presumptive gloss on federal preemption.

VIII
LIVING ESSENTIALS FAILS TO MEET RULE 9(b)'s PLEADING REQUIREMENTS

The bar to Living Essentials' attempt to assert FDCA and FDA claims as a disguised Lanham Act and state law claims is conclusive. In addition, however, Living Essentials' amended counterclaim should be dismissed because it fails to meet Rule 9(b)'s particularity requirements and also fails to plead Lanham Act and §§ 17200 and 17500 standing for the alleged "adulteration," "misbranding" and "mislabeling" it asserts.

Living Essentials' amended counterclaim does not meet the heightened pleading

requirements of Rule of 9(b). Where, as here, Living Essentials' false advertising and unfair competition claims are grounded in alleged fraud, they must be pled with particularity. *Vess v. Ciba-Geigy Corp. USA,* 317 F.3d 1097, 1103-04 (9th Cir. 2003); *see also, Collegenet, Inc. v. Xap Corp.*, 2004 U.S. Dist. LEXIS 21059, at *15-16 (D. Or. Oct. 12, 2004) (finding allegations of unfair competition that were based on a "unified course of fraudulent conduct," were "grounded in fraud" and subject to Rule 9(b)'s particularity requirement); *Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.*, 2009 U.S. Dist. LEXIS 64108, at *23 (C.D. Cal. July 16, 2009) (citing *Vess, supra*, and finding Rule 9(b)'s particularity requirement applied to false advertising claims grounded in fraud); *Wright v. Gen. Mills*, 2009 U.S. Dist. LEXIS 90576, at *17 (S.D. Cal Sept. 30, 2009) (Lorenz, J.) (finding Rule 9(b)'s particularity requirement applies to § 17200 claims).

To satisfy Rule 9(b), Living Essentials must "state the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986). Further, it must set forth **more** than neutral facts necessary to identify the transaction. *Vess, supra,* at 1106. It must also state what is false or misleading about the statement, and why. *Id.* Living Essentials has failed adequately to do so.

The amended counterclaim does nothing more than identify four specific statements that it attributes to Hansen; it then summarily states that each specific statement is false and/or misleading "based on the products' ingredients and generally accepted principles of biochemistry, pharmacology and physiology" (¶¶ 46-49). In each instance, Living Essentials added that Hansen "knew or should have known" the statements were false. (*Id.*) Such summary allegations are insufficient under Rule 9(b) precisely because Living Essentials does not set forth with any particularity what it is about each specific products' ingredients that makes each purported statement false.

Living Essentials further fails to explain how each alleged statement fails to comport with generally accepted principles of biochemistry, pharmacology and physiology, and more importantly, how failure to comply with those principles renders each statement false. Moreover, Living Essentials alleges no facts to show how or why Hansen should have known that each

statement was allegedly false.

Finally, Living Essentials' claims also fail to state the time, place, medium, and identity of the parties to these alleged misrepresentations. Thus, Living Essentials' summary allegations fail to meet the heightened pleading requirement of Rule 9(b). For these reasons, its amended counterclaim should be dismissed.

IX
LIVING ESSENTIALS HAS ALSO FAILED TO PLEAD LANHAM ACT STANDING

The Standard for Lanham Act Standing Under 15 U.S.C. § 1125(a)(1)(B).

In order to establish standing under the Lanham Act's "false advertising" prong, 15 U.S.C. § 1125(a)(1)(B), a party "must allege commercial injury based upon a misrepresentation about a product and also that the injury was 'competitive,' i.e., harmful to the [Living Essentials'] ability to compete with the defendant." *The Jack Russell Terrier Network of N. Cal. v. Am. Kennel Club, Inc.*, 407 F.3d 1027, 1037 n.19 (9th Cir. 2005) (*citing Barrus v. Sylvania*, 55 F.3d 468, 470 (9th Cir. 1995)).

In addition, the Supreme Court decisions in *Bell Atlantic Corporation v. Twombly,* 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009), require Living Essentials to set forth allegations that contain non-conclusory factual content, and the reasonable inferences from that content must plausibly suggest a claim entitling Living Essentials to relief. *Id.*, 129 S.Ct. at 1949. Thus, formulaic recitations of a claim's elements are to be discounted because they do nothing more than state a legal conclusion. *Id.*, at 1951 (*quoting Twombly*, 550 U.S. at 555). Moreover, in order for Living Essentials' claim to be plausible, it must show more than a "sheer possibility that [the] defendant acted unlawfully." *Iqbal*, 129 S.Ct. at 1949 (*quoting Twombly*, 550 U.S. at 557).

Therefore, to establish Lanham Act standing here, Living Essentials must plausibly plead that the "injury [that is the subject of its claims] was competitive, i.e., harmful to [Living Essentials'] ability to compete with [Hansen]." *See Jack Russell,* 407 F.3d at 1037 (*quoting Barrus*, 55 F.3d at 470). Here, Living Essentials complains that it was "injured" by the alleged "adulteration," "misbranding" and "mislabeling" of specific Hansen products. Living Essentials' allegations however, fall far short of *Twombly/Iqbal* pleading standards.

Living Essentials' Amended Counterclaims Cannot Meet the *Twombly* and *Iqbal* Standard.

Applying the *Twombly/Iqbal* pleading standard to the amended counterclaim, it is patently clear that Living Essentials has not plausibly alleged the kind of **competitive** injury (harmful to Living Essentials' ability to compete with Hansen) that *Jack Russell* mandates.

Rather, at most, the amended counterclaim merely alleges that certain Hansen products may compete with Living Essentials' 5-Hour Energy® products. (*See* amended counterclaim at ¶¶ 8, 11-12 (listing 23 broadly disparate Hansen Product lines that purportedly compete with a single Living Essentials' product line—its 5-Hour Energy® drinks)). Establishing the mere possibility of competition, however, is far from enough.

Living Essentials must also allege well-pled facts to show the required connection between the alleged "adulteration," "misbranding" or "mislabeling" of each Hansen product and the inability of Living Essentials' 5-Hour Energy® products to compete with Hansen. Instead, without providing a single supporting well-pled fact, Living Essentials summarily states that it was injured by the alleged misbranding, "both by the direct diversion of sales from Living Essentials to Hansen and by a lessening of the goodwill associated with Living Essentials' products." (¶ 63). Such allegations are wholly conclusory and insufficient for a court to find that Living Essentials is plausibly entitled to relief. *See Iqbal*, 129 S.Ct. at 1949; *see also, Phoenix of Broward, Inc. v. McDonald's Corp.*, 489 F.3d 1156, 1163 (11th Cir. 2007) (a well-pled complaint needs more than an attenuated link between the alleged competitive injury and the alleged misrepresentation). As such, Living Essentials cannot establish the precise nexus required properly to allege § 1125(a)(1)(B) standing.

This is not merely a pleading failure that yet another amendment might cure. Rather, the amended counterclaim makes clear that the required competitive injury connection simply does not exist. For these reasons as well, the amended counterclaim should be dismissed without leave to amend. *See Gallagher v. San Diego Unified Port Dist.*, 2009 U.S. Dist. LEXIS 78955, at *8 (S.D. Cal. Aug. 31, 2009) ("[c]ourt may deny leave to amend the complaint where ... amendment would be futile").

X
LIVING ESSENTIALS LACKS STANDING UNDER CALIFORNIA BUSINESS & PROFESSIONS CODE §§ 17200 AND 17500

For all of the same reasons that Living Essentials lacks standing to bring its Lanham Act claims, it likewise lacks standing to assert claims under Bus. & Prof. Code §§ 17200 and 17500. Actions for relief under §§ 17200 and 17500 may only be prosecuted by a person who has suffered injury in fact **and** has lost money or property as a resolute of a violation of these sections. *See* Bus. & Prof Code §§ 17204, 17535. Injury in fact must be distinct and palpable and not abstract, conjectural, speculative, or hypothetical. *Allen v. Wright*, 468 U.S. 737, 750-52 (1984). Furthermore, the "links in causation" between the injury in fact and the defendant's allegedly wrongful conduct must not be weak. *Id.* at 759. Thus, Living Essentials must show it suffered actual or threatened injury as a result of Hansen's allegedly wrongful conduct. *See id.*

As discussed above, Living Essentials' §§ 17200 and 17500 claims are subject to stringent pleading requirements. Not only are the allegations subject to the *Twombly/Iqbal* standard, but a party alleging unfair business practices under §§ 17200 and 17500 must also "state with reasonable particularity the facts supporting the statutory elements of the violation." *Khoury v. Maly's of Cal.*, 14 Cal.App.4th 612, 619 (1993).

Here, Living Essentials seeks to establish injury in fact and loss of money or property through its summary allegation that Hansen's alleged misbranding practices caused it injury, "both by the direct diversion of sales from Living Essentials to Hansen and by a lessening of the goodwill associated with Living Essentials' products." (¶ 70). The causation link between Hansen's purported actions and Living Essentials' alleged injury is more than weak, it is non-existent. Living Essentials failed to allege a single, well-pled fact sufficient to show **any** correlation between Hansen's branding and advertising practices and the effect that those alleged practices had on Living Essentials' sales or its goodwill or that Living Essentials has plausibly suffered any harm as a direct result of Hansen's allegedly wrongful conduct. In short, Living Essentials lacks standing to bring its § 17200 and § 17500 claims because it has not suffered an injury in fact or lost money or property as a direct result of Hansen's actions.

XI
CONCLUSION

As overwhelming **federal** law demonstrates, Living Essentials may not, either directly or indirectly through California's Sherman Law, pursue alleged violations of the FDCA, or FDA regulations, as either Lanham Act or state law claims. Accordingly, this Court should dismiss its amended counterclaim as a matter of law. In addition, because Living Essentials has not pled, as it must, with Rule 9 particularity or pled standing, either under the Lanham Act or sections 17200 or 17500, this Court should dismiss its amended counterclaim for those reasons as well.

Respectfully submitted,

DATED: October 26, 2009

SOLOMON WARD SEIDENWURM & SMITH, LLP

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CERTIFICATE OF SERVICE

I caused the **HANSEN BEVERAGE COMPANY'S MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS DEFENDANT'S AMENDED COUNTERCLAIM** to be served in the following manner:

Electronic Mail Notice List

The following are those who are currently on the list to receive e-mail notices for this case.

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Manual Notice List

The following is the list of attorneys who are not on the list to receive e–mail notices for this case (who therefore require manual noticing).

No one.

s/ Edward J. McIntyre
EDWARD J. MCINTYRE